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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,333	01/27/2006	Gilad Lavi	S2082/20004	4212
3000 7590 05/14/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER ANDERSON, MICHAEL J	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 05/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

**Office Action Summary**

Application No.

10/566,333

Applicant(s)

LAVI ET AL.

Examiner

Michael J. Anderson

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/31/2006, 9/22/2006 and 9/13/2006.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The references cited have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the Information Disclosure Statement (IDS) Form PTO/SB/08a in compliance with 37 CFR 1.98(a)(1).

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 21 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 21 recite the limitation "said driver protrusions" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 31 depends from claim 21.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 9, 38, 44, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Chevallier (US patent publication No. 2002/0193746 A1) (Chevallier) and/or Jansen (US patent 6,319,233) (Jansen).

6. With regard to claim 1, 9, 38, 44, and 45 Chevallier discloses (abstract; figures 1-8) an injection device (figures 1) comprising: a housing (10) having a proximate end and a distal end, the distal end having an opening therein; a shield (16, 18) slideably coupled to the housing at said distal end thereof; a cartridge barrel (A) within the housing, the cartridge barrel having proximate and distal ends; a needle (14) cannula fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end; a stopper (12) within the cartridge barrel; a driver (12) coupled to the stopper; a spring (30, 32, 22) coupled between the housing and the driver; a driver trigger (12, abstract) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuatable in use to release the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and urges the shield away from the housing so as to cover the needle cannula (abstract).

7. Furthermore, with regard to claim 1, 9, 38, 44, and 45 Jansen discloses (abstract; figures 1-19) an injection device (10) comprising: a housing (26) having a proximate end and a distal end, the distal end having an opening therein; a shield (28) slideably coupled to the housing at said distal end thereof; a cartridge barrel (16) within

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the housing, the cartridge barrel having proximate and distal ends; a needle (18) cannula fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end; a stopper (20) within the cartridge barrel; a driver (22) coupled to the stopper; a spring (30) coupled between the housing and the driver; a driver trigger (48, 58) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuatable in use to release the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and urges the shield away from the housing so as to cover the needle cannula (columns 2, 4, and 6).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70 19-21, 50-52, and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevallier (US patent publication No. 2002/0193746 A1) (Chevallier) and/or Jansen (US patent 6,319,233)

(Jansen) in view of Lavi (US patent publication 2003/0105430) (Lavi) and/or Marshall (US patent No. 5,599,309) (Marshall).

10. With regard to claim 2, 8, 19-21, 50-52, and 58-59, Chevallier discloses an injection device according to claim 1 however, Chevallier may not disclose a means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield. Lavi (figures 37-47) and Marshall (abstract, figure 1, and 6-9) discloses a means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield (abstracts).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated.

11. With regard to claims 3-7, 10-15, 35-37, 46-48, 61, 63-64 and 70, Chevallier discloses an injection device according to claims 1 and 9. However, Chevallier may not disclose the driver trigger being coupled to said shield, wherein movement of the shield inwardly with respect to the housing activates the trigger. Marshall discloses (abstract, figure 1, and 6-9) the driver trigger being coupled to said shield, wherein movement of the shield inwardly with respect to the housing activates the trigger. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was

made to modify the injection syringe of Chevallier as disclosed by Marshall to make the safety shield injection syringe automated.

12. With regard to claims 16-18, 53- 57, 60, 22-25, 39-42, 26, 28-31, 49, 65-66, 69, 27, 62, 32-34, 43 and 67-68, Chevallier or Jansen discloses an injection device according to claim 9 however, Chevallier or Jansen may not disclose a set of supports, injector rods, safety tabs, injector cartridge and viewing window. Lavi (shows in figures 37-47 an injection device with a housing (304), a shield (302), a cartridge barrel (204) with a needle cannula (32), a stopper (38), a driver (208), a spring (20), a driver trigger (24), a release mechanism (48+56) and a titration rod (234)) and Marshall (abstract, figure 1, and 6-9) disclose a set of supports, injector rods, safety tabs, injector cartridge and viewing window. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier or Jansen as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated.

### ***Conclusion***

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 contain many injection syringes with needle shields that are cited in their entirety.

13. Some of the claims repeat the same elements using different wording and have been grouped as follows:



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Group I, claim(s) 1, 9, 38, 44, and 45 are all drawn to a complete injection device.

Group II, claim(s) 2, 8, 19-21, 50-52, and 58-59 are all drawn to injector spring driving means.

Group III, claim(s) 3-7 are all drawn to injector trigger.

Group IV, claim(s) 10-15, 35-37, 46-48, 61, 63-64 and 70 are all drawn to injector shield.

Group V, claim(s) 16-18, 53- 57 and 60 are all drawn to injector housing supports.

Group VI, claim(s) 22-25 and 39-42 are all drawn to injector rod.

Group VII, claim(s) 26, 28-31, 49, 65-66 and 69 are all drawn to injector safety tabs, pins and pattern, leaf spring, or latches.

Group VIII, claim(s) 27 and 62 are all drawn to injector cartridge.

Group IX, claim(s) 32-34, 43 and 67-68 are all drawn to injector viewing window.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson  
Examiner  
Art Unit 3767

MJA  
5/8/2007

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

